

NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

**GUIDELINES FOR APPROVED
PATHOLOGY COLLECTION CENTRES
(REQUIREMENTS FOR MEDICAL PATHOLOGY SPECIMEN
COLLECTION)**

(Third Edition 2013)

NPAAC Tier 3B Document

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Requirements for Medical Pathology Services

Australian Government Department of Health

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The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on matters related to the accreditation of pathology Laboratories and the introduction and maintenance of uniform Standards of practice in pathology Laboratories throughout Australia. A function of NPAAC is to formulate Standards and initiate and promote education programs about pathology tests.

Publications produced by NPAAC are issued as accreditation material to provide guidance to laboratories and accrediting agencies about minimum Standards considered acceptable for good laboratory practice.

Failure to meet these minimum Standards may pose a risk to public health and patient safety.

Scope

The *Guidelines for Approved Pathology Collection Centres (Requirements for Medical Pathology Specimen Collection)* is a Tier 3B NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for Medical Pathology Services*. The latter is the overarching document broadly outlining Standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, Laboratory staff and referrers (both for pathology requests and inter-Laboratory referrals) are safely and satisfactorily met in a timely manner.

Whilst there must be adherence to all the Requirements in the Tier 2 document, reference to specific Standards in that document are provided for assistance under the headings in this document.

This document details the minimum requirements for best practice for all Specimen collection. They apply to Approved Collection Centres, Hospital Collection Points and any collection activity connected to an Approved Pathology Authority. They detail Standards for premises, staffing, equipment, documentation, storage, transport, collection procedures and safety.

Collections provided in settings other than in Approved Collection Centres and Hospital Collection Points may not be able to meet all the physical requirements but should use this document for guidance to best practice.

Abbreviations

ACC	Approved Collection Centre
APA	Approved Pathology Authority
AS	Australian Standard
AS/NZS	Australian and New Zealand Standards
HCP	Hospital Collection Point
ISO	International Organization for Standardization
NPAAC	National Pathology Accreditation Advisory Council
OH&S	Occupational Health and Safety

Definitions

Approved Collection Centre	means a Specimen collection centre for which an approval under section 23DNBA of the <i>Health Insurance Act 1973</i> ¹ is under force.
Approved Pathology Authority	means the same as that in section 3 of the <i>Health Insurance Act 1973</i> .
Hospital Collection Points	means a Specimen collection facility within a <i>recognised hospital</i> ¹ equivalent to an ACC.
Requirements for Medical Pathology Services (RMPS)	<p>means the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, Laboratory staff and referrers (both for pathology requests and inter-Laboratory referrals) are safely and satisfactorily met in a timely manner.</p> <p>The standard headings are set out below –</p> <p>Standard 1 – Ethical Practice</p> <p>Standard 2 – Governance</p> <p>Standard 3 – Quality Management</p> <p>Standard 4 – Personnel</p> <p>Standard 5 – Facilities and Equipment</p> <p style="padding-left: 40px;">A – Premises</p> <p style="padding-left: 40px;">B – Equipment</p> <p>Standard 6 – Request-Test-Report Cycle</p> <p style="padding-left: 40px;">A – Pre-Analytical</p> <p style="padding-left: 40px;">B – Analytical</p> <p style="padding-left: 40px;">C – Post-Analytical</p> <p>Standard 7 – Quality Assurance</p>

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Introduction

Errors in pathology Specimen collection can be a major risk to patient safety in the pathology testing process. The integrity and identification of patient Specimens to be tested depends on the correct collection procedure. A contributory factor to the procedure is an adequate collection facility. This document, together with *Requirements for Medical Pathology Services*, sets out the minimum requirements for best practice for Specimen collection to assure the safety, quality and efficacy of the collection of pathology Specimens for testing.

Following on from the review of the *Guidelines for Approved Pathology Collection Centres (2006)*, the revised Requirements set out Standards which are applicable to Specimen collection.

The assessment of collection centres (ACCs and HCPs) forms part of the national accreditation process.

These Requirements are intended to serve as minimum Standards in the accreditation process and have been developed with reference to current and proposed Australian regulations and other standards from the International Organization for Standardization including:

AS ISO 15189 *Medical laboratories – Requirements for quality and competence*

These Requirements should be read within the national pathology accreditation framework including the current versions of the following NPAAC documents:

Tier 2 Document

- *Requirements for Medical Pathology Services*

Tier 3B Document

- *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials*

In addition to these Standards, Laboratories must comply with all relevant state and territory legislation (including any reporting requirements).

In each section of this document, points deemed important for practice are identified as either ‘Standards’ or ‘Commentaries’.

- A Standard is the minimum requirement for a procedure, method, staffing resource or facility that is required before a Laboratory can attain accreditation — Standards are printed in bold type and prefaced with an ‘S’ (e.g. **S2.2**). The use of the verb ‘**must**’ in each Standard within this document indicates a mandatory requirement for pathology practice.
- A Commentary is provided to give clarification to the Standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a ‘C’ (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a Standard or not.

Note that when comments are expanding on a Standard or referring to other legislation, they assume the same status and importance as the Standards to which they are attached. Where a Commentary contains the word '**must**' then that Commentary is considered to be **normative**.

Please note that all NPAAC documents can be accessed at www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm

While this document is for use in the accreditation process, comments from users would be appreciated and can be directed to:

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1. Premises

(Refer to Standard 1, Standard 5A, and Standard 6A in *Requirements for Medical Pathology Services*)

S1.1 Collection premises must comply with all applicable laws and regulations.

- C1.1(i) The current approval certificate **must** be visibly displayed.
- C1.1(ii) Patients and carers **must not** enter Laboratory testing areas to gain access to the collection rooms.
- C1.1(iii) Easily cleanable surfaces **must** be available for clerical work, Specimen collection and Specimen handling.
- C1.1(iv) Suitable, secure storage area for supplies **must** be available and accessible only to staff.
- C1.1(v) Floor coverings in the immediate collection and storage areas **must** have a non-porous surface.
- C1.1(vi) There should be provision to accommodate carers as required.
- C1.1(vii) Toilet doors should be lockable from the inside and unlockable from the outside in case of emergency. The doors should be removable or open outward for purposes of access.
- C1.1(viii) Hours of operation should be displayed.
- C1.1(ix) Collection areas should have adequate space for furniture to enable patients to be seated or to be recumbent according to medical requirements as well as a work surface for the collection staff.

2. Equipment

(Refer to Standard 4 and Standard 5B in *Requirements for Medical Pathology Services*)

- S2.1 Where complicated procedures e.g. therapeutic venesection, the injection or infusion of any substance are performed, resuscitation equipment must be available for use by trained personnel.
- S2.2 There must be dedicated Specimen storage areas whether at ambient or refrigerated temperature and there must be documentation detailing which Specimens require controlled temperature storage. Suitable, secure refrigerators and/or eskies must be available.
- C2.1(i) Where refrigeration is required, the storage temperature **must** be maintained between 2 and 8 degrees Celsius.
- C2.2(ii) Specimens **must not** be stored with food, drink or pharmaceuticals.
- C2.3(iii) Specimens should be stored for the least possible time prior to transport to the testing Laboratory.
- C2.4(iv) Maximum allowable storage time should be specified in the collection instruction manual, where applicable.

3. Personnel

(Refer to Standard 4 in *Requirements for Medical Pathology Services*)

S3.1 Identification must be worn by all staff.

C3.1 First name or surname or identification number (or any combination of the three) as well as the pathology organisation name should be used as a minimum.

S3.2 Suitable attire must be worn by staff in accordance with the APA's policies.

C3.2 To assist patients, the use of uniforms linking staff to the pathology providers is encouraged.

S3.3 There must be policies regarding customer service, privacy, confidentiality and informed consent available to staff and all staff must be aware of and comply with the policies. The Specimens must be collected in accordance with these policies.

C3.3(i) For particular tests, the requesting practitioner **must** ensure written informed consent is obtained from the patient and this **must** be provided at the collection point for tests specified in technical Requirements e.g. genetic testing.

C3.3(ii) Staff **must** be trained to ensure knowledge of basic first aid measures to deal with situations likely to be encountered in the course of patient Specimen collection.

C3.3(iii) Staff **must** be able to direct patient enquiries regarding access to their results.

C3.4(iv) Consent is implied by the patient's presentation of a request form unless otherwise specified.

4. Documentation/ Instruction

(Refer to Standard 3 in *Requirements for Medical Pathology Services*)

S4.1 Where patients collect their own Specimens they must be provided with instructions in accordance with the collection instructions manual.

C4.1 Instructions should be available in languages or formats relevant to the patient population.

5. Collection Procedures

(Refer to Standard 1, Standard 3, and Standard 6A in *Requirements for Medical Pathology Services*)

- S5.1 The patient must be informed of the procedure about to take place.**
- S5.2 Collection staff must handwash or use alcoholic hand rub, together with glove use in the collection procedure.**
- S5.3 Patients must be instructed on post-procedure care in accordance with the collection instructions manual.**
- S5.4 There must be a policy for the collection of Specimens in the patient's place of residence.**

6. Transport and Storage of Specimens

(Refer to Standard 6A in *Requirements for Medical Pathology Services*)

S6.1 If Specimens are to be retained within the collection centre, safety, Specimen stability and security requirements must be addressed and appropriately documented.

C6.1 The security procedures specified **must** ensure that the Specimens are not accessible to members of the public.

References

1. *Health Insurance Act 1973*, Commonwealth of Australia, Australian Government, Canberra

Bibliography

Australian Commission on Safety and Quality in Healthcare, Healthcare Associated Infection, Sydney, viewed 3 June 2011, <<http://www.safetyandquality.gov.au>>

Further information

Other NPAAC documents are available from:

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